Attorney Docket No. P70650US0

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Knut ADERMANN et al.

Application No. 10/539,627 Patent No. 7655629

Filed: September 19, 2005 Issue Date: February 2, 2010

For PEPTIDES AND THEIR USE FOR THE TREATMENT OF HIV INFECTIONS

RESPONSE TO DECISION ON REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT

Director for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to the Decision on Request for Reconsideration of Patent Term Adjustment and Notice of Intent to Issue Certificate of Correction" mailed January 20, 2011 ("the January 20 Decision"), patentees timely submit the instant response to the January 20 Decision. With all due respect, and as detailed below, the applied Rule 703(f) 271-day "overlap" (in the January 20 Decision) constitutes a newly found fact having what amounts to a retroactive effect that is irreversibly prejudicial against patentees; and, that waiver of the 271-day reduction, or other commensurate relief as determined by the Director, and issuance of a Certificate of Correction accordingly are in order. No fee for the instant response is indicated in the January 20 Decision or is otherwise apparent and, so, none is provided herewith (authority is granted in the accompanying transmittal to charge a deposit account, should a fee be necessary).

Patentees request under 35 USC 154(b)(3)(B)(ii) filed June 7, 2010 ("the §154(b)(3)(B)(ii) request"), acted on by the January 20 Decision, was prompted by the "Decision on Request for Recalculation of Patent Term Adjustment in view of Wyeth and Notice of Intent to Issue Certificate

of Correction" mailed May 13, 2010 ("the May 13 Decision"). There is nothing whatsoever in the May 13 Decision, itself, or in connection with the May 13 Decision recalculation in the record, even mentioning a Rule 703(f) "overlap," let alone actually calculating an "overlap" at 271 days, as done in the January 20 Decision. Indeed, if it were correct, the Rule 703(f) "overlap" should have been calculated and applied in the May 13 Decision.

Accordingly, by the failure to determine the Rule 703(f) 271-day "overlap" pursuant to the May 13 Decision, and by the determination of the Rule 703(f) 271-day "overlap in the January 20 Decision, patentees have been denied a full and fair opportunity to request reconsideration of the Rule 703(f) overlap of 271 days in the §154(b)(3)(B)(ii) request (for reconsideration of the May 13 Decision). The result is prejudicial, in that patentees would need to file yet another Rule 705(b) request due to an error—by the PTO in one or both of the January 20 Decision and the May 13 Decision. Such prejudice is, however, a moot point.

Any prejudice associated with patentees need to file yet another Rule 705(b) request is academic, in that patentees are effectively barred from doing so, statutorily. That is, pursuant to §154(b)(3)(B)(ii), "the Director shall-...(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director" (emphasis added). In other words—patentees are effectively barred because—in effect, the Director is statutorily denied the authority to consider more than "one...request [for] reconsideration of any patent term adjustment."

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In effect, determination of the Rule 703(f) 271-day "overlap in the January 20 Decision inserts the determination into the record, retroactively, prior to patentees filing the §154(b)(3)(B)(ii) request, i.e., as if it were a determination to which patentees had waived any rights to request reconsideration by not doing so in the (filed) §154(b)(3)(B)(ii) request. In this respect, attention is respectfully directed to *American Trucking Ass'ns v. Frisco Transp. Co.*, 358 U.S. 133 (1958), in which the Supreme Court ruled on the authority of an administrative agency to—retroactively, in effect—modify its own earlier decision. Admittedly, the administrative agency was not the PTO, and the ruling is not directly *in point*. Nevertheless, the ruling is instructive, in that the Supreme Court required advance notice to, and time to be heard by, a party that would be adversely effected by the modification—in effect retroactive—of its earlier decision.

Even absent the statutory bar, and again with all due respect, this type of piece meal decision making is obviously unfair, i.e., for the "academic" reasons set forth above. Indeed, under such a piece-meal-decision-making procedure, each and every decision—on petition requesting reconsideration (not barred by statute) of an earlier decision on petition requesting reconsideration—could theoretically "newly find" a mistake in petitioner's favor in that earlier decision; and so, theoretically, require a petitioner to file an endless chain of reconsideration requests (or needlessly seek appellate review).

In view of the foregoing facts and explanation, patentees seek relief in that the PTO waive the reduction of patent term adjustment, under Rule 703(a)(3), by the 271-day "overlap," or other

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commensurate relief as determined by the Director, and issue a Certificate of Correction in accordance therewith.

Respectfully submitted,

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